

APR 05 2013

510(k) Summary of Safety and Effectiveness

<i>Date Summary Prepared</i>	September 12, 2012
<i>Manufacturer/Distributor/Sponsor</i>	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
<i>510(k) Contact</i>	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5333, ext. 1720 Fax: 239/598.5508 Email: courtney.smith@arthrex.com
<i>Trade Name</i>	Fracture Plates
<i>Common Name</i>	Plate, fixation, bone
<i>Product Code -Classification Name CFR</i>	HWC, HTN, HRS 21 CFR 888.8030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
<i>Predicate Device</i>	<i>K011335: Synthes On-third Tubular Plates</i> <i>K102998: Acumed Congruent Bone Plate System</i> <i>K103705 / K111253 / K112437: Low Profile Screw</i>
<i>Purpose of Submission</i>	This traditional 510(k) premarket notification is submitted to obtain clearance for the Arthrex Fracture Plates and the accompanying screws.
<i>Device Description and Intended Use</i>	The Arthrex Fracture Plates are a family of titanium and stainless steel plates and screws. The plates are flat and contoured, ranging from 50 mm to 244 mm in length. The accompanying screws are 2.5mm to 6.7mm in diameter.
<i>Intended Use</i>	The Arthrex Fracture Plates are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, and fibula. The Arthrex Low Profile Screws (2.0-2.4mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the

	<p>ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, and Distal Extremity Plates.</p> <p>The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.</p> <p>The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates.</p> <p>The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, femur and fibula.</p>
<p>Substantial Equivalence Summary</p>	<p>Fracture Plates are substantially equivalent to the predicate Synthes One-Third Tubular Plates (K011335), Acumed Congruent Bone Plate (K102998), and the cleared Low Profile Screws (K103705, K111253, and K112437) in which the basic features and intended uses are the same. Any differences between the Fracture Plates and the predicates are considered minor and do not raise questions concerning safety and effectiveness.</p> <p>The proposed devices are composed of Titanium or Stainless Steel, which is substantially equivalent to the predicate devices.</p> <p>The submitted mechanical testing data demonstrated that the bending, pull-out and torque strength of the proposed devices are substantially equivalent to the bending, pull-out and torque strength of the predicate devices.</p> <p>Based on the indication for use, technological characteristics, and the comparison to the predicate devices, Arthrex, Inc. has determined that the Fracture Plates is substantially equivalent to currently marketed predicate devices.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Incorporated
% Ms. Courtney Smith
Manager, Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108

Letter dated: April 5, 2013

Re: K123241

Trade/Device Name: Arthrex Fracture Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 13, 2013
Received: February 25, 2013

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number (if known): K123241

Device Name: *Arthrex Fracture Plates*

Indications For Use:

The *Arthrex Fracture Plates* are intended to be used for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneous, fibula.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

PAGE 1 of 1

Elizabeth L. Frank -S

Division of Orthopedic Devices

Indications for Use Form

Indications for Use

510(k) Number (if known): K123241

Device Name: *Arthrex Low Profile Screws*

Indications For Use:

The Arthrex Low Profile Screws (2.0-2.4mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist. When used with a plate, the screw may be used with the Arthrex Low Profile, Small Fragment Plates, and Distal Extremity Plates.

The Arthrex Low Profile Screws (2.0-3.0mm cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.

The Arthrex Low Profile Screws (2.5mm and larger, solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula. When used with a plate, the screws may be used with the Arthrex Low Profile, Small Fragment Plates, Fracture Plates, Distal Extremity Plates, Humeral Fracture Plates, and Osteotomy Plates.

The Arthrex Low Profile Screws (3.5mm and larger, cannulated) are intended to be used as stand-alone bone screws for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, wrist, clavicle, scapula, olecranon, humerus, radius, ulna, tibia, calcaneus, femur and fibula.

Prescription Use ☒ AND/OR Over-The-Counter Use ☐

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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